

**AUG 25 2000**

K002271

### **3.0 Summary of Safety and Effectiveness Information**

**SPONSOR:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700  
Contact: Thomas M. Maguire

**DEVICE NAME:** 2.4 mm Cortex Screw, Self-tapping

**CLASSIFICATION:** Class II, Section 888.3040: Smooth or threaded metallic bone fixation fastener

**PREDICATE DEVICE:** Synthes (USA) Kirschner Wire has been commercially available prior to May 28, 1976.

**DEVICE DESCRIPTION:** Fully threaded screw available in multiple lengths, from 6mm to 60mm, having a self-tapping leading end and cruciform head.

**INTENDED USE:** For use in the diaphysis and metaphysis of small and large bones, such as ulna, radius, calcaneus, tarsals, metatarsals, proximal phalanges, carpals, metacarpals, and distal tibia for fracture fixation.

**MATERIAL:** 316L Stainless steel



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 25 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Thomas M. Maguire  
Project Leader, Regulatory Affairs  
SYNTHES (USA)  
1690 Russell Road  
Post Office Box 1766  
Paoli, Pennsylvania 19301

Re: K002271  
Trade Name: 2.4mm Cortex Screw, Self-tapping  
Regulatory Class: Class II  
Product Code: HWC  
Dated: July 25, 2000  
Received: July 26, 2000

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



*for* Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2.0 Indications for Use Statement

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510(k) Number (if known): K002271

Device Name: Synthes (USA) 2.4 mm Cortex Screw, Self-tapping

Indications/Contraindications: Indicated for use in the diaphysis and metaphysis of small and large bones, such as ulna, radius, calcaneus, tarsals, metatarsals, proximal phalanges, carpals, metacarpals, and distal tibia for fracture fixation.


(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use   

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K002271